September 17, 2010

Jay Angoff, Director
Office of Consumer Information and Insurance Oversight
Department of Health and Human Services
Attention: OCIIO-9992-IFC
7500 Security Boulevard
Baltimore, MD 21244-1850

Re: Joint Comments of Gilead Sciences, Harlem United Community AIDS Center, and Project Inform on the Interim Final Rules for Group Health Plans and Health Insurance Issuers Relating to Coverage of Preventive Services (OCIIO-9992-IFC)

Dear Mr. Angoff:

Gilead Sciences, Inc. ("Gilead"),[1] Harlem United Community AIDS Center ("Harlem United"),[2] and Project Inform[3] appreciate this opportunity to comment on the Interim Final Rules for Coverage of Preventive Services under the Patient Protection and Affordable Care Act (the "Interim Final Rules").[4] In specific, we are providing these joint comments to encourage the Department of Health and Human Services ("HHS") to include routine opt-out HIV testing in the Health Resources and Services Administration ("HRSA") guidelines on preventive care and screening for women, as described in the Public Health Services Act ("PHSA") § 2713(a)(4).[5]

As HHS is aware, in 2006, the Centers for Disease Control and Prevention ("CDC") recommended routine, opt-out HIV screening for patients in all health care settings.[6] These recommendations have been endorsed by numerous national professional organizations,

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[1] Gilead is a research-based biopharmaceutical company that discovers, develops and commercializes innovative medicines in areas of unmet need. Gilead's primary areas of focus include HIV/AIDS, liver disease, and serious cardiovascular and respiratory conditions.

[2] Harlem United was founded in 1988, and now provides HIV testing and outreach to 10,000 individuals annually. Harlem United's integrated approach to HIV services and support is renowned as a national model of providing comprehensive HIV care in a community-based setting.

[3] Project Inform, a national HIV/AIDS advocacy organization founded in 1985, is widely respected for its work in helping speed dozens of safe and effective HIV medications to market, educating hundreds of thousands of HIV-positive individuals about HIV care and treatment, and ensuring adequate government funding for health care programs that serve the sickest and poorest people with HIV.

[4] Interim Final Rules for Group Health Plans and Health Insurance Issuers Relating to Coverage of Preventive Services Under the Patient Protection and Affordable Care Act. 75 Fed. Reg. 41,726 (July 19, 2010).

[5] As added by the Patient Protection and Affordable Care Act, Pub. L. 111-148 (Mar. 23, 2010).

[6] Centers for Disease Control and Prevention, *Revised Recommendations for HIV Testing of Adults, Adolescents, and Pregnant Women in Health-Care Settings* (Sept. 22, 2006), *available at* http://www.cdc.gov/mmwr/preview/mmwrhtml/rr5514a1.htm.

including the American Medical Association, the American Academy of HIV Medicine, the National Association of Community Health Centers, the American Congress of Obstetricians and Gynecologists, and the American Academy of Pediatrics, as well as a number of major national HIV advocacy groups. In terms of improving women's health, ensuring proper implementation of the CDC recommendations is increasingly critical, given both the growing number of HIV-positive individuals who are unaware of their status and the fact that nearly 26 percent of all HIV diagnoses in 2008 were of women (an estimated 9,567 individuals nationwide).[7]

We agree with the position taken by HHS in the Interim Final Rules that in certain circumstances, market failures (such as the lack of incentives for insurers to cover preventive services and the failure of markets to capture the full societal benefits of preventive services) lead to underutilization of preventive services.[8] Extensive recent research demonstrates that routine opt-out HIV screening is precisely one of these circumstances. While routine opt-out HIV screening leads to greatly improved patient outcomes in a cost-effective manner, it has nevertheless been severely underutilized as a public health tool. We thus believe that expanded insurance coverage of preventive services (such as those subject to PHSA § 2713(a)), can lead to expanded utilization as well as to substantial benefits to both patients and society.[9] Including routine opt-out HIV screening as a mandatory-coverage preventive service would be a major step towards reducing the market failures that are currently hindering critical clinical responses to the HIV/AIDS epidemic.

For these reasons, Gilead, Harlem United, and Project Inform strongly urge that HHS include routine opt-out HIV screening in the HRSA guidelines on preventive care and screening for women. Furthermore, while we acknowledge that the United States Preventive Services Task Force ("USPSTF") currently assigns a neutral "C" rating to routine HIV screening, we observe that this rating neither binds HHS in promulgating the HRSA guidelines, nor reflects the current state of the research on the value of routine HIV screening. In light of the overwhelming recent evidence that such screening decreases HIV transmission, improves patient outcomes, and is cost effective, we would urge HHS to encourage the USPSTF to revisit its outdated neutral rating for routine HIV screening.

I. Expanding Access to Routine Opt-Out HIV Screening is Critical to Addressing the HIV/AIDS Epidemic in the United States.

As HHS is aware, HIV/AIDS remains a serious public health threat in the United States. The CDC estimates that more than 1.1 million Americans are currently living with HIV, and that

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[7] Centers for Disease Control, *HIV/AIDS Surveillance Report, 2008, available at* http://www.cdc.gov/hiv/surveillance/resources/reports/2008report/table2a.htm

[8] *See* 75 Fed. Reg. 41,731.

[9] *See* 75 Fed. Reg. 41,733 (*citing* Jonathan Gruber, *the Role of Consumer Copayments for Health Care: Lessons from the RAND Health Insurance Experiment and Beyond*, Kaiser Family Foundation (Oct. 2006)).

more than 56,000 new infections occur each year (40 percent higher than previous estimates).[10] More than 14,000 Americans die from AIDS each year,[11] and recent estimates show that two-thirds of new infections – and approximately one-fifth of all Americans living with HIV – remain undiagnosed.[12]

Expanding access to routine screening is critical to combating the HIV/AIDS epidemic, because knowing one's HIV status both enables infected individuals to be connected with care sooner, and dramatically reduces the likelihood of infected individuals exposing others to HIV. In 2006, the CDC recommended that routine, opt-out HIV screening be adopted as the prevailing standard of care for patients in all health care settings.[13] These recommendations were well supported by clinical and epidemiological evidence in 2006, and subsequent research has made even more clear the benefits of routine HIV screening. As articulated below, significant evidence, in the form of peer-reviewed, published literature, demonstrates that routine screening would reduce transmission of HIV, improve patient outcomes, and be cost effective.

The importance of expanded HIV screening was further underscored earlier this summer in the recently promulgated National HIV/AIDS Strategy for the United States ("National Strategy"). The National Strategy notes that "[u]nless we take bold actions, we face a new era of rising infections, greater challenges in serving people living with HIV, and higher health care costs."[14] The National Strategy also acknowledges that the current approach to HIV testing is failing to meet the goal of reducing the number of new infections, noting that "[a]n estimated 21 percent of people with HIV in the United States do not know their status," and that "[s]tudies show that people who do not know that they are HIV-positive are more likely to engage in risk behaviors associated with HIV transmission.[15] In light of these realities, the National Strategy

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[10] *See* CENTERS FOR DISEASE CONTROL, *HIV Prevalence Estimates – United States, 2006*, 57 MORBIDITY & MORTALITY WKLY REP. 1073-1076 (2008); Centers for Disease Control, *Estimates of New HIV Infections in the United States* (Aug. 2008) *available at* http://www.cdc.gov/hiv/topics/surveillance/resources/factsheets/pdf/incidence.pdf.

[11] *See* Kaiser Family Foundation, *Survey of Americans on HIV/AIDS* (May 2006), *available at* http://www.kff.org/kaiserpolls/pomr050806pkg.cfm; Mahajan A., et al. *Consistency of State Statutes With the Centers for Disease Control and Prevention HIV Testing Recommendations*. ANNALS OF INTERNAL MEDICINE (2009) 150(4):263-269.

[12] *See* CENTERS FOR DISEASE CONTROL, *HIV Prevalence Estimates – United States, 2006*, 57 MORBIDITY & MORTALITY WKLY REP. 1073-1076 (2008); Wolf LL & Walensky RP, *Testing for HIV Infection in the United States*. CURRENT INFECTIOUS DISEASE REPORTS (2007) 9:76-82.

[13] Centers for Disease Control, *Revised Recommendations for HIV Testing of Adults, Adolescents, and Pregnant Women in Health-Care Settings*, 55 MORBIDITY & MORTALITY WKLY REP. 2-13 (2006), *available at* http://www.cdc.gov/mmwr/preview/mmwrhtml/rr5514a1.htm.

[14] *See* White House Office of National AIDS Policy, NATIONAL HIV/AIDS STRATEGY FOR THE UNITED STATES, at vii (July 13, 2010), *available at* http://www.whitehouse.gov/sites/default/files/uploads/NHAS.pdf.

[15] *Id*. at 7.

declares that "[t]o prevent HIV, we should strive to ensure that all people living with HIV know their HIV status" (emphasis supplied).[16]

II. Inclusion of Routine Opt-Out HIV Screening in the HRSA Guidelines on Preventive Care and Screening for Women is Supported by Overwhelming Evidence.

By including routine opt-out HIV screening in the HRSA guidelines on preventive care and screening for women, HHS would help not only increase the number of women who would learn their HIV status and be brought into care, but would help reduce the number of new HIV transmissions. Indeed, a recent study modeling the effect of universal, voluntary, annual HIV testing and treatment for those who test positive found that such a program could reduce annual new infections by 95 percent within ten years.[17] As the arbiter of the minimum requisite preventive care that millions of American women are entitled to receive, HRSA is well-positioned to play an integral role in this effort. By including routine opt-out HIV screening under the auspices of PHSA § 2713(a), HRSA would increase access to such screening, allowing many women to become aware of their HIV status in time to seek life changing, ore even life saving, treatment.

A. The Impact of HIV on American Women Has Been Growing Steadily.

The impact of HIV on American women has been growing steadily over the past two decades: The CDC estimates that women now account for 26 percent of all new HIV/AIDS diagnoses, with an estimated 9,567 new diagnoses in 2008 alone.[18] This compares to 20 percent of diagnoses in 2000, and only 8 percent of diagnoses in 1985.[19] The CDC also estimates that in 2007, women accounted for 23 percent of all people living with HIV/AIDS (an estimated 105,260 individuals), and nearly 27 percent of all deaths of people with AIDS (an estimated 4,672 individuals).[20]

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[16] *Id*. at 16 (noting particularly that all HIV-negative people at high-risk for infection should be tested for HIV "at least once a year" and that evidence suggests that people unaware of their HIV-positive status for an extended period of time tend to enter care too late to receive the full benefits of treatment).

[17] *See* Granich RM, et al. *Universal voluntary HIV testing with immediate antiretroviral therapy as a strategy for elimination of HIV transmission: a mathematical model*. LANCET (2009) 61697-9.

[18] Centers for Disease Control, *HIV/AIDS Surveillance Report, 2008, available at* http://www.cdc.gov/hiv/surveillance/resources/reports/2008report/table2a.htm

[19] Kaiser Family Foundation, *HIV/AIDS Policy Fact Sheet* (Sept. 2009), *available at* http://www.kff.org/hivaids/upload/6092-07.pdf.

[20] Centers for Disease Control, *HIV/AIDS Surveillance Report, 2008, available at* http://www.cdc.gov/hiv/surveillance/resources/reports/2008report/table16a.htm, http://www.cdc.gov/hiv/surveillance/resources/reports/2008report/table12a.htm

Even more concerning is evidence that women may not be receiving the medical information about HIV they need. Research has found that 24 percent of women assumed (almost always erroneously) that an HIV test was a routine part of a medical exam, and that only 44 percent of non-elderly women had discussed HIV/AIDS with a health care provider.[21] Furthermore, HIV/AIDS disproportionately affects women of color, with Black women comprising an estimated 66 percent of all HIV cases among women ages 13 and older in 2008, but only 12 percent of the U.S. female population.[22]

B. Knowing One's HIV Status Decreases HIV Transmissions.

Current research indicates that widespread routine HIV screening will significantly reduce the spread of HIV, because people who know that they are HIV positive are 3.5 times less likely to infect others than those who do not know that they are HIV positive.[23] Indeed, between 50 and 70 percent of new sexually transmitted HIV infections are transmitted by undiagnosed individuals.[24] If everyone knew their HIV status, research indicates that the number of sexually transmitted HIV infections could be reduced by 30 percent.[25] Nor is this projection simply hypothetical: A 2008 analysis of historical trends suggests that roughly 6,000 new HIV infections were averted between 2001 and 2004 due to the increased number of people who had learned their HIV status.[26]

Moreover, because patients with lower viral loads are less likely to transmit the virus than those with higher levels of virus, patients receiving HIV treatment regimens that suppress viral loads are less likely to transmit HIV to others.[27] Earlier treatment has also been endorsed by the updated HHS guidelines (December 2009), which now recommend commencing HIV treatment once a patient's CD4 cell count falls below 500 per cubic mm (previously, the threshold was

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[21] Kaiser Family Foundation, *Survey of Americans on HIV/AIDS* (2004).

[22] Centers for Disease Control, *HIV/AIDS Surveillance Report, 2008*, *available at* http://www.cdc.gov/hiv/surveillance/resources/reports/2008report/table4a.htm

[23] Janssen RS & Valdiserri RO. *HIV Prevention in the United States: Increasing Emphasis on Working with Those Living with HIV*. JOURNAL OF ACQUIRED IMMUNE DEFICIENCY SYNDROMES (2004) 37(2):S119-S125.

[24] Marks G, et al. *Estimating Sexual Transmission of HIV From Persons Aware and Unaware That They Are Infected with the Virus in the USA.* AIDS (2006). 20(10):1447-1450.

[25] Centers for Disease Control, *Revised Recommendations for HIV Testing of Adults, Adolescents, and Pregnant Women in Health-Care Settings*, 55 MORBIDITY & MORTALITY WKLY REP. 2-13 (2006), *available at* http://www.cdc.gov/mmwr/preview/mmwrhtml/rr5514a1.htm.

[26] Pinkerton SD, et al. *Infections Prevented by Increasing HIV Serostatus Awareness in the United States, 2001 to 2004.* JOURNAL OF ACQUIRED IMMUNE DEFICIENCY SYNDROMES (2008). 47(3):354-357.

27 *See* Luuk G, et al. *CD4 Cell Counts of 800 Cell/mm3 or Greater After 7 Years of Highly Active Antiretroviral Therapy Are Feasible in Most Patients Starting with 350 Cells/mm3 or Greater*. JOURNAL OF ACQUIRED IMMUNE DEFICIENCY SYNDROMES (2007). 45(2):183-192; Quinn TC et al. *Viral Load and Heterosexual Transmission of Human Immunodeficiency Virus Type 1*. N. ENGL. J. MED. (2000). 342(13):921-929.

only 350 per cubic mm).[28] It is therefore even more crucial than ever that individuals learn their HIV status and get connected to care as early as possible.

C. Early Diagnosis Improves Patient Outcomes.

Greater access to routine opt-out HIV screening will result in more diagnoses at an earlier stage of the disease, when treatments are more cost effective and more likely to improve health outcomes. Tremendous advances in the treatment of HIV now mean that if diagnosed early enough, HIV can frequently be managed as a chronic condition. Indeed, people diagnosed with HIV who receive appropriate and timely antiretroviral treatment can often expect to live three decades or more.[29] Unfortunately, a large proportion of HIV-positive individuals continue to go undiagnosed until the very late stages of the disease, thus depriving them of the benefits of earlier treatment. In fact, 33 percent of women diagnosed with AIDS were diagnosed within one year of testing positive for HIV,[30] while an astonishing 30 to 40 percent of all patients are diagnosed with AIDS at the same time they test positive for HIV.[31] And up to five percent of HIV-positive individuals only learn of their condition in their very last month of life.[32]

Additional state and local data bear out these grim statistics. In New York City in 2007, one in four HIV-positive individuals were diagnosed with AIDS within 31 days of being diagnosed with HIV.[33] In South Carolina in 2008, 41 percent of AIDS cases studied were diagnosed with 12 months of the patients' first HIV tests — yet even more troubling, almost 75 percent of late-diagnosed patients had visited a healthcare clinic at least four times prior to their diagnosis, but had not been tested for HIV.[34] In short, in the absence of widespread routine testing, large numbers of women will continue to learn their HIV status only when it is too late for treatment to be optimally effective.

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[28] HHS Panel on Antiretroviral Guidelines for Adults and Adolescents. *Guidelines for the Use of Antiretroviral Agents in HIV-1-Infected Adults and Adolescents* (2009). *Available at* http://www.aidsinfo.nih.gov/ContentFiles/AdultandAdolescentGL.pdf

[29] Kitahata M, et al. *Effect of Early vs. Deferred Antiretroviral Therapy for HIV on Survival*. NEW ENGL. J MED. (2009) 360:1815.

[30] Centers for Disease Control. *HIV/AIDS Surveillance Report, 2007*, (2009), *available at* http://www.cdc.gov/hiv/topics/surveillance/resources/reports/2007report/default.htm.

[31] Wolf LL & Walensky RP. *Testing for HIV Infection in the United States*. CURRENT INFECTIOUS DISEASE REPORTS (2007) 9:76-82.

[32] Walensky RP. *Implications and Implementation of the New HIV Testing Guidelines.* HIV Management 2007: The New York Course (2007), *available at* http://www.medscape.com/viewarticle/556378.

[33] New York City Department of Health and Mental Hygiene. *HIV Epidemiology & Field Services Semiannual Report* (2008) 3(1):2.

[34] Duffus W, et al. *Missed Opportunities for HIV Diagnosis and Care – South Carolina, 1997-2005*. 55 MORBIDITY & MORTALITY WKLY REP. 1269-1272 (2006).

D. Routine Opt-Out HIV Screening is Cost Effective.

In part because treatment costs are significantly lower when HIV is detected early, routine opt-out HIV screening is cost effective. Not only are the health care costs of HIV patients two to three times higher when the disease is more advanced,[35] but untreated HIV infection can be associated with the development of many non-AIDS-defining diseases, including cardiovascular disease, kidney disease, liver disease, and cancer.[36] A review of several studies on HIV screening for the American College of Physicians concluded that HIV screening remains cost-effective even when HIV prevalence in the population is as low as 0.1 percent.[37] HIV prevalence in the United States as a whole is 0.4 percent, and in some urban areas it is as high as 3 percent.[38] Indeed, one prominent study noted that "[w]hen we look at the cost-effectiveness of HIV screening compared with the cost-effectiveness of screening of other diseases that are standard of care in the United States, we actually see that it's more cost-effective to screen for HIV infection than to screen for breast cancer, colon cancer, hypertension, or diabetes"[39] (emphasis supplied).

III. Inclusion of Routine Opt-Out HIV Screening in the HRSA Guidelines on Preventive Care and Screening for Women Would Increase Access to Such Screening.

Pursuant to PHSA Section 2713(a)(4), HRSA is tasked with developing guidelines that establish the preventive care and screening procedures for women that health care insurers must cover without cost-sharing. As described above in Part II of this joint comment letter, routine opt-out HIV screening is currently underutilized, resulting in an unacceptably high number of new infections reported annually, increased transmission rates, poorer health outcomes for those who are late diagnosed, and increased costs to the health care system.

Moreover, at present, misinformation, cultural challenges, and concerns about stigma often create barriers that prevent individuals from seeking and receiving HIV testing. Patients

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[35] *See, e.g.*, Chen Y, et al. *Distribution of Health Care Expenditures for HIV-Infected Patients.* CLINICAL INFECTIOUS DISEASES (2006) 42:1003-1010; Schackman B. et al. *The Lifetime Cost of Current Human Immunodeficiency Virus Care in the United States*. MEDICAL CARE (2006) 44:990-997.

[36] Lohse N, et al. *Survival of Persons With and Without HIV Infection in Denmark, 1995-2005*. ANNALS OF INTERNAL MEDICINE. (2007) 146: 87-95.

[37] *See* Qaseem A, et al. *Screening for HIV in Health Care Settings: A Guidance Statement From the American College of Physicians and HIV Medicine Association*. American College of Physicians Clinical Practice Guidelines (2009) 150(2):125-131.

[38] *See* CENTERS FOR DISEASE CONTROL, *HIV Prevalence Estimates – United States, 2006*, 57 MORBIDITY & MORTALITY WKLY REP. 1073-1076 (2008); *see also* Wash., D.C. Dep't of Health, *District of Columbia HIV/AIDS Epidemiology Update 2008* (Feb. 2009), *available at* http://dchealth.dc.gov.

[39] Walensky RP. *Implications and Implementation of the New HIV Testing Guidelines.* HIV Management 2007: The New York Course (2007), *available at* http://www.medscape.com/viewarticle/556378.

may feel uncomfortable requesting an HIV test from their health provider, and similarly, providers may be hesitant to affirmatively recommend such a test.[40] Individuals may also not even understand (or believe) that they are at risk for HIV, and thus may have no reason to consider — much less request — an HIV test.[41] And cultural and language barriers can often further compound the difficulty of ensuring that those who are often in the greatest need of HIV testing actually get tested.[42] By establishing HIV testing as a routine medical service for women, HRSA can help significantly reduce many of these barriers, by sending women the powerful message that routine opt-out HIV testing is a standard component of basic medical care. Finally, lack of adequate insurance coverage for testing — another common barrier — would be directly addressed by including HIV testing in the HRSA Guidelines.[43]

In sum, incorporating routine opt-out HIV screening into the HRSA guidelines would slow the spread of HIV, conserve fiscal resources, and most importantly, save and extend lives of thousands of women. For these reasons, Gilead, Harlem United, and Project Inform strongly urge HRSA to include routine opt-out HIV screening in its guidelines.

IV. A USPSTF Rating of "A" or "B" for Routine HIV Screening Would Facilitate Coverage of Routine HIV Screening under Medicare and Private Insurance.

Finally, Gilead, Harlem United, and Project Inform encourage HHS to engage in a dialogue with the USPSTF regarding the need for the USPSTF to review its neutral rating of routine HIV screening for patients not considered high risk.

The USPSTF currently gives an "A" rating to HIV screening of people at "an increased risk for HIV infection," and a "C" rating to HIV screening of people not considered "at increased risk."[44] Following the 2006 publication of the CDC's recommendations supporting routine screening, the USPSTF reconsidered its rating for routine screening of people not considered at increased risk, but elected in April 2007 to retain its "C" rating.[45] Notably, a "C" rating means that the USPSTF "found at least fair evidence that [the service] can improve health outcomes,"

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[40] *See, e.g.*, Emmers-Sommer T. et al. *Patient–Provider Communication About Sexual Health: The Relationship with Gender, Age, Gender-stereotypical Beliefs, and Perceptions of Communication Inappropriateness.* SEX ROLES (2009). 60(9-10):669-681; Grant K & Ragsdale K. *Sex and the 'Recently Single': Perceptions of Sexuality and HIV Risk Among Mature Women and Primary Care Physicians.* CULTURE, HEALTH & SEXUALITY (2009). 10(5):495-511.

[41] *See, e.g.*, Marks G et al. *Meta-analysis of high-risk sexual behavior in persons aware and unaware they are infected with HIV in the United States: implications for HIV prevention programs.* J. ACQUIRED IMMUNE DEFICIENCY SYNDROME (2005). 39(4):446-53.

[42] *See, e.g.*, Valenti WM. *Expanding HIV Testing: Overcoming Physician Barriers.* AIDS READER (2009). 19:201-203.

[43] Barclay L. *Application of HIV Testing Guidelines in Clinical Practice Reviewed.* AMERICAN FAMILY PHYSICIAN (2009). 80:1441-1444.

[44] *See* USPSTF, *Screening for HIV, at* http://www.uspreventiveservicestaskforce.org/uspstf/uspshivi.htm.

[45] *See id.*

with "fair" evidence defined as evidence that is "sufficient to determine effects on health outcomes, but [whose strength] is limited by the number, quality, or consistency of the individual studies, generalizability to routine practice, or indirect nature of the evidence on health outcomes" (emphasis supplied).[46]

As articulated in this joint comment letter, a significant body of peer-reviewed research has been published since 2006, establishing the clinical, societal, and economic benefits of routine HIV testing. We believe that the quality of this research significantly improves upon the evidence base that led the USPSTF to establish a "C" rating in 2006. We also believe that the extent of the research now available would allay any concerns of USPSTF that their rating could be disproportionately influenced by a small number of studies.

Moreover, the USPSTF's exceptionally cautious approach here is strikingly similar to its reaction to the 1996 CDC recommendation that all pregnant women (not just those perceived to be at high risk) receive routine HIV testing, in order to limit perinatal transmission.[47] Despite this CDC recommendation and existing research as to the efficacy of such testing,[48] USPSTF delayed for nearly a decade in upgrading its "C" rating for HIV testing of all pregnant women, adopting an "A" rating only in 2005.[49] While we greatly respect USPSTF's established record of giving careful consideration to the empirical evidence, we also believe that now, as then, the evidence overwhelmingly supports an "A" rating for routine opt-out HIV testing.

Unfortunately, in the absence of a consistent message from the CDC and the USPSTF on this issue, it remains possible that the USPSTF's outdated "C" rating will be misinterpreted as implying that — despite contemporary evidence to the contrary — certain barriers remain to establishing routine opt-out HIV testing as an essential preventive service for women as well as for men. Indeed, we note that numerous insurers and public health programs base their coverage of preventive services on USPSTF ratings. As such, delays in updating outdated USPSTF ratings can have adverse consequences for both public health policy and for individuals who would benefit from a USPSTF rating that reflects current evidence and research. We therefore urge HHS to encourage the USPSTF to reconsider its current rating for routine opt-out HIV screening, in light of the overwhelming evidence that such screening decreases HIV transmission, improves patient outcomes, and is cost effective.

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[46] USPSTF, *Grade Definitions Prior to May 2007*, *at* http://www.uspreventiveservicestaskforce.org/uspstf/gradespre.htm.

[47] Centers for Disease Control. *U.S. Public Health Service Recommendations for Human Immunodeficiency Virus Counseling and Voluntary Testing for Pregnant Women*, 44 MORBIDITY & MORTALITY WKLY REP. 1-15 (1995) *available at* http://www.cdc.gov/mmwr/preview/mmwrhtml/00038277.htm.

[48] *See, e.g.*, Centers for Disease Control. *Recommendations of the U.S. Public Health Service Task Force on the Use of Zidovudine to Reduce Perinatal Transmission of Human Immunodeficiency Virus*, 43 MORBIDITY & MORTALITY WKLY REP. (1994); Connor EM, et al. *Reduction of Maternal-Infant Transmission of Human Immunodeficiency Virus Type 1 with Zidovudine Treatment.* N. ENGL .J. MED. (1994) 331:1173-80; European Collaborative Study. *Risk Factors for Mother-to-Child Transmission of HIV-1*. LANCET (1992) 339:1007-12.

[49] USPSTF, *Screening for HIV*, *available at* http://www.uspreventiveservicestaskforce.org/uspstf05/hiv/hivrs.htm.

V. Conclusion.

Gilead, Harlem United, and Project Inform appreciate the opportunity to provide these joint comments on the Interim Final Rules regarding the importance of incorporating routine opt-out HIV testing into the HRSA guidelines on preventive care and screening for women. We appreciate your time and attention to these joint comments, and we would be pleased to provide any additional information that may be of value in addressing the issues discussed above.

Sincerely,

Rekha Ramesh
Associate Director, Government Affairs
Gilead Sciences

Patrick J. McGovern
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Dana Van Gorder
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